

Regulatory Coordination Teleconference
October 6, 1999

1. Approval of Minutes are approved 3-0

2. New Members

Susan Smith
Dr. Prince A. Kassim

3. Interim meeting 12/14-7 In DC. Our meeting 12:30-2 12/16. Details on the web

4. Scope of testing

Carl Kircher is creating a common list from the 11 accredited authority
SDWA- federal regulated and unregulated analytes
CWA - Priority pollutant list
Problems with solid waste -no common list
CLP - Contracts
Serious discussions have yet to begin on Air
Hopes to have it posted by deadline for first round of lab applications

George Avery proposed a possible change to simplify the standard by changing the scope to Program/Matrix/Technology.

Current Analyte specific schemes does cause problems...Proficiency Testing, Inspections, etc.

This affects reciprocity...some states have additional requirements. Unless a common way to accredit is found, full reciprocity cannot be a reality. Also, the lab goal of 1 Accrediting Authority would not be met.

George Avery will prepare draft language regarding future changes. (See attachment)

5. Infrastructure

NELAP Infrastructure

Fields of testing - above
Auditor training - progress made. Structure is supposed to ready, proposal at interim.
- Checklist should be in the final version today
- Some states have stopped audits until January
Proficiency - NIST list theoretically by October 25
Lab Education - Outreach Committee
National Database - Where does this stand?

Interstate Compact - Does the requirement for reciprocity create an interstate compact requiring Congressional approval

State Needed Infrastructure

State Databases - these need to interface with the NELAC database and PT providers

State Internal training and staffing

FLA - sent out 198 applications, received back 6, draft checklists being tested.... mini training program in Florida until the real courses actually exist. First trial balloon assessments in November.

5. Carl Kircher - Will tackle regulatory agenda

6. Michael Miller - Will send out a letter on state regulations and legislation

7. Tabled internal consistency until next meeting.

Comments have been received and will be considered to see if the current process is adequate for coordination.

8. EPA Agency-wide QA System

Does this look affect NELAP?

How does it affect the standards?

Will readdress next meeting

Next Meeting Monday, 2nd week of November, 8th noon EST

Participants

Michael Miller

George Avery

Carl Kircher

Susan Smith

Ronald Peters

Ilona Taunton

NELAC Regulatory Coordination

Scope of Accreditation

Program-Matrix-Technology Basic unit of accreditation

The current practice of Program-Method-Analyte is not consistent with smoothly facilitating reciprocity. State-to-state differences in regulations do not allow a 100% compatible list of compounds, therefore a primary accreditation in one state is unlikely to satisfy the need for accreditation in all state. It is possible that a laboratory would require multiple primary accrediting authorities under the NELAC standard for the same test method. An often-voiced goal of NELAC is to allow the commercial laboratories "one-stop-shopping" for accreditation. The scope of accreditation should be designed in a way which facilitates reciprocity while ensuring data quality.

The fundamental goal of laboratory accreditation is to allow the regulating body to have some assurance of the quality of data generated by the laboratory. The current standards attempt to do this through certifying every method for every analyte. A legitimate question may be raised as to whether this is necessary. Additionally, this type of regulation will prove to be a clumsy anachronism in the event of the adoption of a performance based methods system (PBMS) which would end the practice of prescribed methods.

The scope of accreditation needs to be simplified to facilitate coordination between the regulations of the various NELAC Accrediting Authorities. In order to do so, we propose the following.

The Regulatory Coordination Committee recommends that the Program Policy and Structure, Quality Systems, and Proficiency Testing Committees revisit the issue of scope of accreditation and adopt a plan whereby the scope is defined on the basis of the Program, Matrix, and Analytical Technology. This should include a list of indicator analytes for each technology sufficient to indicate the general competency of the laboratory to meet basic data quality requirements. Accreditation for an Analytical Technology based on these indicators should be considered as accreditation for any analyte or parameter appropriate to that technology. These indicator analytes should be required to be included in any proficiency testing sample submitted by a laboratory as part of the requirements for accreditation for that Program, Matrix, and Technology.